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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/505,898	02/17/2000	Kirti Dave	065733/2262	7146

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EXAMINER

WINKLER, ULRIKE

ART UNIT PAPER NUMBER

1648

DATE MAILED: 08/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/505,898

Applicant(s)

DAVE ET AL.

Examiner

Ulrike Winkler, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-62 is/are pending in the application.
- 4a) Of the above claim(s) 48-53 and 57-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-47, 54-56 and 60-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Continued Prosecution Application

The request filed on July 3, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/505,898 is acceptable and a CPA has been established. An action on the CPA follows.

The Amendment filed July 3, 2002 (Paper No. 28) in response to the Office Action of April 8, 2002 is acknowledged and has been entered. Claims 44-62 are pending and claims 44-47, 54-56 and 60-62 are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Drawings

Formal drawings and photographs submitted February 4, 2002 fail to comply with 37 CFR 1.84. Please see the Draftsperson's review form PTO-948. Correction is required.

Specification

Applicant is required to update the status (pending, allowed, ect.) of all parent priority applications in the first line of the specification

Claim Rejections - 35 USC § 103

The rejection of claim 44-46, 54-56 and 60-62 under 35 U.S.C. 103(a) **is maintained** for reason of record. An additional reference is now included with the prior rejection in order to address some of the new limitations added in the amendment of Paper No. 28. Therefore, claims

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44-46, 54-56 and 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oprandy et al. (Journal of Clinical Microbiology, 1990, see IDS #5), Huang et al. (U.S.Pat. No. 5,712,172) and WHO Bulletin (Bulletin of the World Health Organization, 1996, see IDS #5).

The instant invention is drawn to a method of analyzing an arthropod sample for an agent that may cause disease in humans. The method (claim 44) contains the following steps: (a) obtaining the arthropod sample, (b) treating the sample to expose the analyte from the arthropod, (c) contacting the liquid permeable support which contains a capture reagent with the sample from the previous step (d) allowing liquid to flow vertically through the support by capillary action, and (e) detecting the presence of the analyte. Claims 45-46, 54-56 and 60-62 contain the following additional limitations: the detection moiety, the placement of the analyte specific reagent, the arthropod is a mosquito, the liquid permeable support contains a control area, the analyte specific reagents are monoclonal antibodies, or gold and latex labeled antibodies.

Applicant's arguments are that Oprandy et al. does not teach detection of an arthropod sample without a prefiltration step and the Huang et al. reference does not teach the dipstick construction as now claimed. Applicant equates a latter-flow device to require horizontal use (specification page 12, lines 6-10) and therefore the instantly claimed vertical flow via capillary action is different from the device of Huang et al. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include

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knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Oprandy et al. teach a dot-blot immunobinding assay to detect arthropod-borne agents. The method includes isolating the sporozoite from the mosquito, treating the sporozoite with a detergent to expose the analyte (see materials and methods). Alternately, sporozoite containing mosquitoes were homogenized together in the presence of detergent before spotting onto the filter. An antibody to detect the circumsporozoite protein was used to assay for the presence of the etiologic agent (see figure 2). The titration of the arthropod vector with SDS liberates the antigen. The references also teaches that this same technique can be used for other arthropod – vectored etiologic agents (see page 1703, column 2, last paragraph). The reference does not teach applying the sample to a dipstick device for the detection of the analyte.

Huang et al. teach the use of a lateral flow device for the detection of an analyte in a single step. It is important to point out that lateral flow does not equate to horizontal, nowhere in the patent is there any reference as to the positioning of the device during the detection phase. Lateral flow in the scope of the patent refers to the side-to-side movement of the liquid that is applied to the porous material, such as nitrocellulose. Capillary flow is the result of surface tension. It is the surface tension that moves water through the material; this is regardless of the positioning of the device vertical/horizontal as the water will move from the wetted area to the dry area by way of wicking action. The Huang et al. device contains a sample receiving region which is in direct contact with the liquid sample that contains the analyte, a separate analyte detection region and an end flow region all made of porous material which wicks the liquid through the analyte detection region (see Huang et al. claim 1). The analyte detection region

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includes labeling reagents, a capture reagent and a control reagent. The device can be used for the detection of analytes directly from a biological sample. The reference teaches a method of setting up the test strip, using the appropriate controls and utilizing colored detection agent. The physical construction of the device is the same as the instantly claimed dipstick. The reference also teaches the various detection moieties that can be used with the analyte detection reagent. The reference does not teach detecting an etiologic agent from a mosquito sample.

WHO Bulletin teaches a dipstick assay for the detection of a malarial antigen found in the blood of an infected patient. Here the following steps are used: a blood sample is collected, then the blood is mixed with a lysing agent, the dipstick is placed vertically in the sample and the sample is rapidly taken up by capillary action, a detection agent is then added to sample well, the dipstick is washed and the dipstick is analyzed for the presence of a positive reaction (see figure 1 and page 48 column 2, last paragraph). The dipstick construction contains a reagent control as well. The method steps do not require a prefiltration step of the sample to remove cell debris from the whole blood lysates. The reference teaches the detection of a blood stage malarial antigen, the reference does not teach the detection of a mosquito stage antigen from a mosquito sample.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the analyte detection reagents as taught by Oprandy et al. and apply them to the device taught by Huang et al. and the WHO bulletin. One having ordinary skill in the art would have been motivated to do this because in order to determine the risk of arthropod-vector disease spread it is necessary to survey the insect population for these etiologic agent. This information is important to assess the efficacy of insect control and abatement programs. One

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having ordinary skill in the art would have a high expectation of success in applying the antibodies and the methods of exposing the analyte using detergents as taught by Oprandy et al. and formulate them into the device as taught by Huang et al. and the WHO Bulletin. Therefore, the instant invention is obvious over Oprandy et al., Huang et al. and the WHO Bulletin.

The rejection of claim 44-46, 47, 54-56 and 60-62 under 35 U.S.C. 103(a) as being unpatentable over Oprandy et al. (Journal of Clinical Microbiology, 1990, from applicant's IDS), Huang et al. (U.S.Pat. No. 5,712,172) and WHO Bulletin (Bulletin of the World Health Organization, 1996, see IDS #5) in view of Rattanarithikuln et al. (American Journal of Tropical Medicine, 1996, from applicant's IDS) and Sithiprasasna et al. (Annals of Tropical Medicine and Parasitology, from applicant's IDS).

The instant invention is drawn to a method of analyzing an arthropod sample for an agent that may cause disease in humans. The method (claim 1) contains the following steps: (a) obtaining the arthropod sample, (b) treating the sample to expose the analyte from the arthropod, (c) contacting the liquid permeable support which contains a capture reagent with the sample from the previous step (d) allowing liquid to flow vertically through the support by capillary action, and (e) detecting the presence of the analyte. Claims 45-47, 54-56 and 60-62 contain the additional limitation of the detection moiety, the placement of the analyte specific reagent, detection of multiple analytes (proteins) from different arthropod carried agents, the arthropod is a mosquito, the liquid permeable support contain a control area, the analyte specific reagents are monoclonal antibodies, or gold and latex labeled antibodies.

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The relevance of Oprandy et al., Huang and WHO Bulletin has been discussed above. Claim 47 includes a method whereby multiple analyte specific capture reagents are used in a single assay. The references of Rattanarithikuln et al. and Sithiprasasna et al. both teach ELISA capture assay for different analyte samples found in mosquitoes, specifically against antigens of malaria and dengue. Both references teach utilizing multiple monoclonal antibodies to different species of parasites or viral strains.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the antibody detection reagents as taught by Oprandy et al., Rattanarithikuln et al. and Sithiprasana et al. and apply them to the device taught by Huang and the WHO Bulletin. One having ordinary skill in the art would have been motivated to do this because in order to determine the risk of arthropod-vector disease spread it is necessary to survey the insect population for the etiologic agent. This information is important to assess the efficacy of insect control and abatement programs. One having ordinary skill in the art would have a high expectation of success in applying the antibodies and the methods of exposing the analytes using detergents and formulating them into a device that utilizes the antibody-analyte interaction. Therefore, the instant invention is obvious over Oprandy et al., Huang et al. and WHO Bulletin in view of Rattanarithikuln et al. and Sithiprasasna et al.

Conclusion

No claims allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294.

The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Ulrike Winkler, Ph.D. 8/26/02